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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,032	12/01/2000	Brian F. Berg	24763-1C	2568

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EXAMINER	
NAJARIAN, LENA	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/728,032	BERG, BRIAN F.	
	Examiner	Art Unit	
	Lena Najarian	3626	MW

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2000*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20001201*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it exceeds 150 words and is more than one paragraph. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 101

2. Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth in a two-prong test of:

(1) whether the invention is within the technological arts; and

(2) whether the invention produces a useful, concrete, and tangible result.

For a claimed invention to be statutory, the claimed invention must be within the technological arts. Mere ideas in the abstract (i.e., abstract idea, law of nature, natural phenomena) that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as

opposed to social sciences, for example) and therefore are found to be non-statutory subject matter. For a process claim to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts.

In the present case, claims 1-20 only recite an abstract idea. The recited steps of exemplary claim 1 of merely receiving a pharmaceutical, acquiring accounts receivable data, and ensuring the pharmaceutical is provided to the patient does not apply, involve, use, or advance the technological arts since all of the recited steps can be performed in the mind of the user or by use of a pencil and paper.

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. In the present case, the claimed invention provides covered entities with a method of dispensing and managing the delivery of pharmaceuticals and pharmaceutical services. Although the recited process produces a useful, concrete, and tangible result, since the claimed invention, as a whole, is not within the technological arts as explained above, claims 1-20 are deemed to be directed to non-statutory subject matter.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 17 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Cunningham.

(A) Referring to claim 17, Cunningham shows a method of transacting business with a participating pharmacy, a manufacturer and a patient comprising the steps of:

ordering a product from a manufacturer on behalf of a participating pharmacy wherein the product is for a patient of the participating pharmacy (column 2, lines 24-33 of Cunningham);

acquiring by the manufacturer or in connection with the manufacturer from the participating pharmacy an account associated with the ordering of the product and the patient (column 2, lines 24-33 of Cunningham); and

managing a delivery of the product to the patient (column 2, lines 28-33 of Cunningham).

(B) Referring to claim 18, Cunningham shows that the pharmacy collects payment for the delivery of the pharmaceutical product (column 12, lines 5-8 and 13-18 of Cunningham).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham (US 6,055,507 A) in view of Tarter et al. (US 5,704,044 A).

(A) Referring to claim 1, Cunningham shows a method of providing pharmaceutical product samples comprising the steps of (see abstract of Cunningham):

receiving a product trial media resulting from an order received on behalf of a participating provider for the benefit of a patient (column 9, lines 20-21 and column 2, lines 33-36 of Cunningham);

acquiring an accounts receivable associated with the product trial media (column 3, lines 28-32 & 45-50 and column 12, lines 13-18 of Cunningham);

ensuring the product trial media is provided to the patient (column 3, lines 9-12 of Cunningham).

Cunningham does not disclose acquiring by a manufacturer or in connection with the manufacturer an accounts receivable of the patient.

Tarter discloses the purchasing of accounts receivables from participating pharmacies on the basis of the credit status of the relevant payors and obligors (column 9, lines 64-67); the Examiner interprets accounts receivable of "payor/obligor" to be a form of "accounts receivable of the patient."

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Tarter within Cunningham's method. The motivation for doing so would have been to provide discounted rates to participating providers (column 10, lines 1-5 of Tarter).

(B) Referring to claim 2, Cunningham does not show the collection of payment on behalf of the patient.

Tarter discloses that pharmacies rely on the payment practices and creditworthiness of the payors and obligors to collect for services provided to patients by a third party payment plan (column 1, lines 44-53 of Tarter).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to implement a third party payment plan into Cunningham's method. The motivation for doing so would have been to allow insurers to pay on behalf of the patients (column 1, lines 48-52 of Tarter).

(C) Referring to claim 3, Cunningham discloses that participating pharmacies will receive a dispensing fee (column 3, lines 38-41 of Cunningham).

(D) Referring to claims 4 and 5, Cunningham does not disclose providing of a report to the participating pharmacy associated with providing the product trial media, providing of a report to the participating pharmacy associated with an activity of the accounts receivable, and selling the accounts receivable back to the participating pharmacy.

Tarter discloses that payors provide obligors with management reports and send service providers, along with payment, a report outlining which transactions have been handled and positively adjudicated in the indicated processing cycle (column 3, lines 22-29 of Tarter).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Cunningham's system to include providing reports. The

motivation for doing so would have been to allow providers the opportunity to request reports for the purpose of keeping track of the various activities (column 10, line 14 of Tarter).

(E) Referring to claim 6, Cunningham discloses that the participating pharmacies will manage one or more prescriptions of the patient (column 2, lines 55-65 of Cunningham).

(F) Referring to claim 7, Cunningham does not disclose the selling of the accounts receivable back to the participating pharmacy.

Tarter discloses a third party payment system in which service providers look directly to insurers or obligors for primary payment (column 1, lines 44-47 of Tarter).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Cunningham's system to include a third party payment system since the pharmaceutical industry is already primarily a third party payment system. The motivation for doing so would have been for the providers to satisfy their financial obligations (column 1, lines 37-41 of Tarter).

7. Claims 9-14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tarter et al. (US 5,704,044 A) in view of Cunningham (US 6,055,507 A).

(A) Referring to claim 9, Tarter discloses providing a patient products, comprising the steps of:

receiving an identification number associated with a patient and a prescription number (column 4, lines 43-50 of Tarter);

ordering the prescription using a credit of the insurer (column 1, lines 37-40 of Tarter); and

acquiring by a manufacturer or in connection with the manufacturer an accounts receivable associated with the patient (column 9, lines 64-67 of Tarter).

Tarter does not disclose that the ordered product is dispensed to the patient.

Cunningham discloses that the ordered product is dispensed to the patient (column 2, lines 44-48 of Cunningham).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Cunningham within Tarter's method. The motivation for doing so would have been to efficiently distribute the products to patients (column 2, lines 44-45 of Cunningham).

(B) Referring to claim 10, Tarter discloses that service providers look directly to insurers or other obligors for primary payment in addition to collecting optional co-payments directly from the patients (column 1, lines 43-46 of Tarter).

(C) Referring to claims 11 and 12, Tarter discloses that after a patient presents a pharmacy with a prescription, the pharmacist utilizes his in-house prescription system and gathers necessary information about the prescription, the patient, and his insurance coverage (column 5, lines 5-8 of Tarter).

(D) Referring to claims 13, 14, and 16, Tarter does not disclose providing a fee to the participating pharmacy for acquiring the accounts receivable, wherein the fee is less

than an expense associated with the product, and the product is dispensed to the patient at a patient defined location.

Cunningham shows that a fee is provided to the participating pharmacy for acquiring the accounts receivable (column 3, lines 39-42 of Cunningham) and the fee is less than an expense associated with the product (column 3, 51-54 of Cunningham). Cunningham shows that the product is dispensed to the patient at a patient defined location (column 10, lines 54-57 and figure 7E of Cunningham).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Cunningham within Tarter. The motivation for doing so would have been to compensate the participating pharmacy for their services (column 3, lines 39-42 of Cunningham), to be cost effective (column 3, lines 51-54 of Cunningham), and to provide the product to the patient efficiently (column 2, lines 44-46 of Cunningham).

8. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham as applied to claims 17 and 18 above, and further in view of Tarter et al. (US 5,704,044 A).

(A) Referring to claim 19, Cunningham does not disclose collecting a payment from an insurance of the patient for the delivery to offset a debit associated with the account.

Tarter discloses that the service providers look to the insurers for payment (column 5, lines 54-57 and column 1, lines 43-52 of Tarter).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Tarter within Cunningham. The motivation for doing so would have been to have the insurance pay for the delivery as opposed to the patient (column 5, lines 54-55 of Tarter).

(B) Referring to claim 20, Cunningham does not disclose reporting an activity associated with the account.

Tarter discloses the generation of periodic summary reports for service providers (column 31, lines 35-47 of Tarter).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Tarter within Cunningham. The motivation for doing so would have been to provide the providers with summary reports containing pertinent information on a regular basis (column 31, lines 35-40 of Tarter).

9. Claims 8 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tarter et al. in view of Cunningham as applied to claims 1 and 9 above, and further in view of Everhart (US 5,956,689 A).

Cunningham and Tarter fail to teach that the pharmaceutical product is associated with hemophilia and that it is for the treatment of a Hemophiliac.

Everhart teaches that hemophilia is a rare chronic disease and that drugs are used for its treatment (column 1, lines 13-22, column 4, lines 31-60, and column 5, lines 29-40 of Everhart).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the feature of Everhart with Cunningham and Tarter. The motivation for doing so would have been to have the system be used primarily by those having the rare chronic disease hemophilia (column 1, lines 13-17 of Everhart).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches an integrated pharmaceutical accounts management system and method (US-2002/0002495 A1); a method of providing and billing for medical services (US-2003/0046107 A1); an automated system for selecting and delivering packages from a storage area (US-5593267 A); and a system and method for drug management (US-6021392 A). Other references cited but not relied upon include US-6073104 A and US-5550734 A.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is (703) 305-0260. The examiner can normally be reached on Monday - Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703) 305-9588. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

In
9-20-04

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